

Informed Consent Form

A Randomized, Controlled Trial of a Telephone-Based Developmental Care Coordination System

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UNIVERSITY OF CALIFORNIA LOS ANGELES STUDY INFORMATION SHEET

AMP: ACHIEVING MY POTENTIAL RESEARCH STUDY

Dr. Paul Chung from the Department Of Pediatrics at the University of California, Los Angeles (UCLA) and the Kaiser Permanente School of Medicine are partnering with [REDACTED] to conduct a research study.

You and your child were selected as a potential participant because your child is scheduled for an upcoming 1 to 3 year old well child doctor's check-up and your child is 11-42 months of age. Your participation in this research study is voluntary.

Why is this study being done?

This research study is being done to better understand early childhood development, and how parents can best learn about and access developmental and behavioral services for their children.

What will happen if I take part in this research study?

If you volunteer to participate in this study, the researcher will ask you to do the following:

- Participate in 4 interviews:
 - Answer questions about your child's development – how they are learning, growing, and behaving, as well as questions about your household, like languages spoken at home and your education. We will also ask about your family's experience with the COVID-19 pandemic.
 - These questions will be asked via telephone – today or at study enrollment, and again 6 months, 1 year, and 2 years later.
 - A summary of your answers about how your child is learning, growing, and behaving will be provided to your child's doctor after today's interview.
- You will be asked to provide permission for us to access your child's medical record to look at information related to their development.
 - To provide this permission, you will be asked to complete an important study document online, so internet access is needed – the link to the

HIPAA authorization form can be sent to you via text on your smart phone or via email.

- Agree to be randomly assigned to an early childhood development care coordination intervention.
 - Study participants in this intervention will be connected to a child development care coordination specialist via telephone.
 - The specialist will talk about their child's development as well as any evaluations or services their child might benefit from.
 - The specialist will also help connect the participant and their child to agencies that provide these services.
 - We will provide your child's developmental screening information, your contact information and general information about your household to the care coordination specialist so that they can best help you and your child.
- For research purposes with, your permission, one question about your family's experiences with COVID-19 will be audio recorded.
 - You have the right to review the audio to determine whether it should be edited or erased.
 - Even if you decline audio recording, you can still remain in the study.
- Agree to receive monthly tips about child health, such as about child safety, sleeping and eating habits.

How long will I be in the research study?

You will be in the study for two years. The interviews will take place today, in 6 months, and again in 1 year and 2 years. The interviews will take from about 25 minutes to about 45 minutes to an hour. Today's interview should take about 45 minutes.

Are there any potential risks or discomforts that I can expect from this study?

- You may experience minor discomfort in talking about concerns related to early childhood development.

Are there any potential benefits if I participate?

- You may learn more about your child's development
- The results of your child's developmental screening will be provided to your child's doctor
- If you are randomly selected to be connected to the early childhood developmental care coordination specialist, you may receive help being connected to agencies that provide developmental and behavioral evaluations and services.
- The results of the study may help us understand the best ways for parents and children to access and receive early childhood developmental care.

Will I be paid for participating?

You will receive up to a total of \$90 for your participation in this research:

- \$25 for completing today's interview,
- \$15 for completing an interview in 6 months
- \$25 for completing an interview in one year
- \$25 for completing an interview in two years

The cash incentive will be mailed to you within 1-2 weeks of each interview.

Will information about me and my participation be kept confidential?

- Any information that is obtained in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of keeping in a locked room and in a password protected/encrypted database, only the research team will have access to.
- Information about you is protected by a federal Certificate of Confidentiality. This means that we can't be forced to release information about you for any legal proceeding, even if a court of law asks. The Certificate allows us to use information about you for purposes of this research. There are limits to this protection. The Certificate does not protect your information when: you or your family voluntarily release information about yourselves or if you consent to release of information.

What are my rights if I take part in this study?

- You can choose whether you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, it will not affect your child's care at [REDACTED], there will be no penalty to you, and no loss of benefits to which you and your child were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?

- **The research team:**
If you have any questions, comments, or concerns about the research, you can talk to the one of the researchers. Please contact: Dr. Paul Chung (Principal Investigator) at 626-564-3741 or Dr. Bergen Nelson (Co-Investigator) at [REDACTED]
- **UCLA Office of the Human Research Protection Program (OHRPP):**
If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.